

March 28, 2003

Ms. Rebecca Kane
Environmental Protection Agency
Office of Enforcement and Compliance Assurance
MS 2222A
1200 Pennsylvania Avenue NW
Washington DC 20460

Dear Ms. Kane,

Pharmacia Corporation (NYSE:PHA) is a top-tier global pharmaceutical company whose innovative medicines and other products save lives and enhance health and wellness. Pharmacia's 43,000 people work together with many diverse stakeholders to bring these benefits to people around the world, and to create new health solutions for the future. On July 15, 2002, Pharmacia and Pfizer Inc. (NYSE:PFE) announced the signing of a definitive agreement providing for Pfizer to acquire Pharmacia in a stock-for-stock transaction that is expected to close in the first quarter of 2003.

Pharmacia is commenting on the EPA Office of Enforcement and Compliance Assurance (OECA) November 20, 2002, announcement of the 60-day comment period on its new web site, Enforcement and Compliance History Online (ECHO), which contains searchable, facility-level enforcement and compliance information. We offer our comments because many Pharmacia facilities are included in the database, and it is important that data offered to the public be correct and presented in a manner that facilitates accurate interpretation.

Pharmacia fully supports the comments and concerns raised by PhRMA (Pharmaceutical Researchers and Manufacturers Association) in the separate submission from that group. We have elected not to repeat those comments, but we urge careful consideration be given to them. In addition, we offer the following comments, presented in the order of the outline EPA provided at 67 FR 70080.

I. Does the site provide meaningful and useful information about the compliance and enforcement program? [EPA question (1)]

A. Data Availability and Accuracy

Inaccurate Data

Pharmacia found significant inaccurate data regarding our facilities. The database includes 26 facilities currently owned and operated by Pharmacia. Of these,

- Ten were not included in the list generated from a search for "Pharmacia"

- Five facilities that are not part of Pharmacia were included in the list generated from a search on “Pharmacia” (this number does not include those facilities that include the word Pharmacia as part of their name)
- Eleven contained errors regarding compliance status
- Four contained errors associated with TRI, SIC code or facility address

Thus, the reports for a total of 22 out of 26 of our facilities contained at least one error.

SARA 313 data

Pharmacia found errors in facility summary data for facilities subject to this reporting requirement.

Because TRI (Toxic Release Inventory) data is accessed by clicking on the SARA 313 facility identifier and the summary page does not indicate that data is available within the system, many users may not even be aware that the information is there.

ECHO format of the TRI data is not at all straightforward. We found that the format of EPA’s TRI website is much more user-friendly than ECHO.

By including the data in ECHO rather than simply referencing the other database, EPA has created extra unnecessary work for itself by maintaining two databases for essentially the same data, has increased the opportunity for data errors and has actually increased the administrative burden on the regulated community since facilities have two systems to review to verify that publicly available data is accurate.

For these reasons, we recommend that instead of restating TRI information in ECHO, EPA should simply provide either a link or instructions for accessing the data from EPA’s TRI web site. Users can then obtain data from an easier system, one with which many people are already familiar. This solution would reduce EPA’s total level of effort to make the data available, reduce the burden on the regulated community, improve data accuracy and be more user-friendly.

Review of ECHO Updates

Judging by the volume of errors currently in the system, facilities should be given an opportunity to confirm data when EPA plans significant modifications or additions to the site. When EPA is making simple corrections or updates, facility review may not be warranted. However, when EPA plans wholesale changes, such as adding an entire new regulatory program or previous years’ data, the facilities should have an opportunity to confirm the accuracy of the information before it is made public.

A. Data Interpretation

Less-Than Signs

When we reviewed the database, the program did not recognize less-than symbols, which are frequently used on DMRs (discharge monitoring report) when analytical results are less than a detection limit. If the database reports a less-than detection limit as an actual value, it is inaccurate and misleading.

Date of Last Inspection

Because the ECHO system contains data for finite periods of time, if an inspection has not occurred during that time period, the "date of last inspection" field should state "N/A" or "None" rather than "Never." "Never" extends beyond whatever time period might be covered by the reported data. Careful attention to wording of this sort would help avoid potentially alarming misinterpretations.

VIII. What additional features, content and/or modifications should improve the site? [EPA question (4)]

The web site should include a directory of EPA and state regulatory contacts, as the report contains considerable information that is either incorrect, outdated or somehow misleading. When people at some of our facilities contacted state agencies (air, water and waste) about information in the ECHO database, they were unaware of its contents or their origins. There needs to be clear direction on how to obtain information confirmation.

Establishment of state points of contact for ECHO matters might be helpful since most submissions are made at the state level. EPA indicated at its November 18, 2002, public meeting that it now has 125 "data stewards," mainly in the states, ready to process corrections. These people would receive and respond to requests through the centralized error correction mechanism in the ECHO site.

IX. Were your facility reports accurate? [EPA question (5) (A)]

As described above, Pharmacia found significant errors in the data for our 22 of 26 facilities in the system. Errors included:

1. "In compliance" vs. "in violation" status by quarter for all regulatory programs.
2. Specific DMR data errors, which included mishandling of less-than signs and individual pollutant amounts.
3. Compliance schedules listed as "no sched" or violation when the facility was complying with the schedule.
4. Violations for programs during quarters before programs were in effect (e.g. MACT).
5. Violations for Title V when facilities had applied for Title V permits that had not yet been acted upon by state agencies. A facility cannot be in violation of a permit that has not been issued.

6. Violations of programs that are not applicable.
7. Ongoing noncompliance past the date when the violation was resolved.

IV. If you did need to submit an on-line error report, was the error reporting process easy to use? [EPA question (5) (B)]

Pharmacia facilities that discovered errors have begun (and in some cases completed) the correction process. Some facilities are working directly with program contacts at their state regulator agency; others are using the on-line system. Our experience to date with the on-line system has been that it is relatively straightforward to use. In some cases, EPA has addressed our notifications within a matter of days. For others, we are still waiting for replies with proposals for resolution.

When our facilities have contacted their state agencies, regulators have not always been aware of what information is contained in ECHO or where it might have originated. Some regulators have been unaware that ECHO existed. Others did not know how EPA had obtained certain erroneous information, and some didn't know the identity of the state ECHO contact. In order to improve accuracy and to facilitate the correction process, EPA should consider additional training or awareness campaign for both EPA and state employees.

Pharmacia appreciates the opportunity to comment on EPA's ECHO web site. Should you have any questions regarding these comments, please contact the undersigned at 269-833-8544.

Sincerely,

Corrine L. Kupstas
Director, Environment
Global Environment, Safety and Health

Cc: Bill Whitlock – Pharmacia
Tom White – PhRMA